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Attorney Docket No. 15966-703 (Cura-203)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Padigaru, *et al.*

SERIAL NUMBER: 09/800,321

EXAMINER: Misook Yu

FILING DATE: March 5, 2001

ART UNIT: 1642

FOR: NOVEL PROTEINS AND NUCLEIC ACIDS ENCODING SAME

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132**

I, Michael Jeffers hereby declare and state as follows:

1. I am employed by CuraGen, Inc., the assignee of this application. My title is Group Leader. I received a Ph.D. in Biomedical Sciences in 1993 from the New York University Medical Center. I was a post-doctoral fellow in the laboratory of Dr. George Vande Woude at the National Cancer Institute from 1993 to 1999.
2. I have read, and am familiar with, the contents of the United States Patent Application entitled "Novel Proteins And Nucleic Acids Encoding Same", serial number 09/800,321, which was filed March 5, 2001. I understand the pending claims are directed to a polypeptide comprising SEQ ID NO:4.
3. I am aware that the Examiner has issued an Office Action dated July 3, 2003. In particular, I understand that the Examiner has rejected the pending claims under 35 U.S.C. §§ 101 and 112, contending that the pending claims are not supported by either a specific and substantial asserted utility or a well-established utility.
4. I make this declaration to rebut the Examiner's assertion, with which I do not agree. It is my belief and professional scientific determination that the

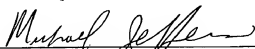
claimed compositions have a specific and substantial utility due to the following facts.

5. I have performed, or have had performed under my supervision, experiments detecting expression of the protein SEQ ID NO:4. FACS analysis was performed on T47D, MCF-7, MDA-MB-231 and OVCAR-3 cell lines which exhibited expression of the nucleic acid encoding polypeptide SEQ ID NO:4 by RTQ-PCR. The ACHN cell line, which expresses little or no nucleic acid encoding SEQ ID NO: 4 as determined by RTQ-PCR, served as a negative control. Cells were washed with Ca and Mg-free 1X PBS (Media Tech, MT 21-040-CV) and removed from plates using Versene (Invitrogen 15040-066). Cells were washed twice with ice-cold FACS buffer (1X PBS, 4% FBS) and resuspended in 100µL of antibody at various concentrations (5, 2, and 1 µg/mL). Anti-NOV XX antibody was affinity-purified rabbit polyclonal antibody generated following immunization with a peptide corresponding to amino acid residues 87-97 of SEQ ID NO: 4. Purified rabbit immunoglobulin served as a negative control. Cells were mixed and incubated at 4°C for 30 minutes. After washing cells twice with 1 mL ice-cold FACS buffer, PE-conjugated goat anti-rabbit secondary antibody (Jackson ImmunoResearch; Cat# 111-036-017) was added at a dilution of 1:100 and cells were incubated at 4°C for 30 minutes. Cells were then washed twice with 1 mL ice-cold FACS buffer and fixed with 400 µL 1% formaldehyde in PBS (Sigma F 1635). Analysis was performed using a FACSCalibur™ flow cytometer (Becton Dickinson, Franklin Lakes, NJ).
6. Results are presented in Table 1. Breast cancer cell lines T47D, MCF-7 and ovarian carcinoma cell line OVCAR-3 were found to express polypeptide SEQ ID NO:4 as detected by anti SEQ ID NO:4 polyclonal antibody. Specifically T47D expressed SEQ ID NO:4 at a level resulting in a GeoMean shift of 29.2 as compared to 7.6 for control staining. MCF-7 showed expression at 10.3 compared to 4.8 and OVCAR-3 expression

*data not in Gerlach declaration*

was measured at 16.8 compared to 12.7. (The ACHN cell line which was previously shown to not express nucleic acid encoding SEQ ID NO:4, also did not show evidence of expression of polypeptide SEQ ID NO:4 as the GeoMean measured for cells treated with anti-SEQ ID NO:4 antisera was 7.3 compared to 4.9 for control preparations.

7. These results support the previous results and show that particular cancer types differentially express the SEQ ID NO:4 polypeptide which is therefore useful for differentiating such diseased cells from others. Thus, it is my opinion and belief that the Examiner should withdraw the rejection and allow the pending claims.
8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

  
Michael Jeffers, Ph.D.

Signed at New Haven, CT  
this 30<sup>th</sup> day of Dec, 2003



TABLE 1

Cell line:		T47D	MCF7	OVCAR-3	ACHN
% Relative RNA expression		3.2	100	8.1	0
Antisera:					
Secondary antisera only (control)		11.3	3.1	10.8	8.1
Rabbit IgG (negative control)	5 ug/ml	7.6	4.8	12.7	4.9
Anti SEQ ID NO:4	5 ug/ml	29.2	10.3	16.8	7.3